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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,030	08/02/2005	Stephen George Edward Barker	117-554 (AMK)	6763
23117	7590	07/27/2009	EXAMINER	
NIXON & VANDERHYE, PC			ANDERSON, GREGORY A	
901 NORTH GLEBE ROAD, 11TH FLOOR				
ARLINGTON, VA 22203			ART UNIT	PAPER NUMBER
			3773	
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			07/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,030	BARKER, STEPHEN GEORGE EDWARD	
	Examiner	Art Unit	
	GREGORY ANDERSON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 June 2009.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 23-35,39-41 and 43-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 23-35,39-41 and 43-45 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Response to Arguments

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "with or without an attached suture" renders the claim indefinite.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 23-27, 29, 31-35, 39-41, 43, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eberbach 5,366,460 in view of Miller 6,837,893.

Eberbach discloses an applicator assembly comprising: a laparoscopic port (Col. 7 II. 20-24), a deployment sleeve 10 for passing down the laparoscopic port, a plunger 42 for location within the sleeve to extend from a proximal to a distal end thereof, a sheet of surgical material 14 which can be folded, or collapsed, for location at and fully

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within the distal end of the deployment sleeve, and an actuating means to unfold or erect the sheet of surgical material following expulsion of the sheet of surgical material from the distal end of the deployment sleeve as a result of longitudinal movement of the plunger within the deployment sleeve (Col. 8 ll. 48-51). Eberbach further discloses a pulling means operative to apply a pull force to the sheet of surgical material following deployment (Col. 8 ll. 48-51). Eberbach further discloses the pulling means being a suture (Col. 8 ll. 38-40). Eberbach further discloses the sheet of surgical material, in use, is encased and protected within the deployment sleeve during the manipulation procedure to position the sleeve at the termination of the opening after which the sheet of surgical material is expelled by the plunger to be erected to close behind and over the internal area of the opening (Col. 7 ll. 20-24). Eberbach further discloses the sheet of surgical material comprises a surgically compatible mesh (Col. 6 ll. 38-47). Eberbach further discloses the sheet of surgical material being a flat flexible sheet and includes radial ribs forming more rigid but resilient arms through which, when the sheet of surgical material is forced to a collapsed or folded configuration, the sheet of surgical material is caused to open out to restore the flat form (Fig. 38). Eberbach further discloses the unfolding of the sheet is effected or assisted through a suture which pulls the sheet upward towards the applicator (Col. 8 ll. 48-51). Eberbach further discloses the sheet including ribs which have preformed fold creases to facilitate collapse to the predetermined configuration (Fig. 41). Eberbach further discloses the sheet of surgical material including ribs that have a memory acting to restore the sheet to a flat form (Col. 17 ll. 65-68). Eberbach further discloses suturing the patch into its final location. It is

well known in the art to use a suture needle to deliver a suture. Eberbach further discloses the deployment sleeve being dimensioned to pass down the port (Col. 7 ll. 20-24). Eberbach further discloses the port having a nominal diameter of 5 to 10 mm (Col. 10 ll. 11-13). Eberbach further discloses other instruments for use in laparoscopic surgery (Col. 7 ll. 59-64). Eberbach further discloses the surgical mesh comprising polypropylene (Col. 6 ll. 41-42). Eberbach further discloses the sheet of surgical material being circular (Fig. 39).

However, Eberbach does not disclose the deployment sleeve being provided with an external flange defining an insertion stop for the deployment sleeve in the laparoscopic port to control the length of insertion of the sleeve in the port.

Miller discloses a flange 55 for controlling the distal movement of the delivery tube. Miller further discloses flange 60 on the plunger for controlling its depth.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Eberbach with the flange of Miller in order to control the amount of depth that the device can be inserted in the tissue as taught by Miller (Col. 9 ll. 26-29).

6. Claims 28, 30, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eberbach in view of Miller and further in view of Himpens et al. 5,397,331.

Eberbach in view of Miller discloses the invention essentially as claimed as discussed above.

However, Eberbach in view of Miller does not disclose the sheet of surgical material being made wholly of PTFE.

Himpens et al. discloses the entire sheet is wholly of PTFE (Col. 5 ll. 2-4). Himpens et al. further discloses the opening being affected through the properties of the sheet material itself (Col. 5 ll. 4-13). Himpens et al. further discloses the sheet of surgical material comprising a non-stick material on an innermost surface adjacent the applicator (since the Himpens et al. device can be made from PTFE it will inherently inhibit adhesion).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Eberbach in view of Miller with the material of Himpens et al. since it has been held that the substitutions of a known equivalent material is obvious; *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Conclusion

7. Applicant's amendment filed 8/12/08 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY ANDERSON whose telephone number is (571)270-3083. The examiner can normally be reached on Mon-Thurs 9:30AM-3PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory A Anderson/
(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773

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